SUMMARY

oritavancin

TENKASI 1,200 mg

powder for concentrate for solution for infusion

Inclusion on list: First listing

Range supplement

Adopted by the Transparency Committee on 28 August 2024

Summary of opinion

Favourable opinion for reimbursement in the treatment of acute bacterial skin and skin structure infections (ABSSSI), only in adult patients with infections of a certain degree of seriousness, for whom a staphylococcal aetiology is demonstrated or suspected (suppurative infections) and methicillin resistance is demonstrated or strongly suspected.

No clinical added value of the new form with a dose strength of 1,200 mg of oritavancin compared to the form already available with a dose strength of 400 mg of oritavancin.

Transparency Committee's conclusions

Clinical Benefit

- Skin and skin structure infections are composed of a very varied range of clinical entities, for which the development conditions, treatment and prognosis are variable, from ulcers, infected wounds, abscesses, erysipelas and diabetic foot ulcers through to the most serious forms, including bacterial cellulitis and necrotising fasciitis.
- This is a curative medicinal product.
- The efficacy/adverse effects ratio is high in less serious infections (erysipelas/non-necrotising cellulitis, infected wounds and major skin abscesses), primarily caused by staphylococci, including methicillin-resistant staphylococci.

  In more serious forms requiring critical or intensive care treatment and/or due to multi-drug resistant bacteria, the efficacy/adverse effects ratio is yet to be specified.
- There are alternative therapies, including for multi-drug resistant bacteria.
- This is a second-line treatment.

Haute Autorité de Santé – Communication and Information Department

5 avenue du Stade de France – 93218 SAINT-DENIS LA PLAINE CEDEX – France. Tel.: +33 (0)1 55 93 70 00

➔ Public health benefit

TENKASI (oritavancin) 1,200 mg is unlikely to have an additional impact on public health.

The Committee considers that the clinical benefit of TENKASI (oritavancin) 1,200 mg is substantial in the treatment of acute bacterial skin and skin structure infections (ABSSSI), only in adult patients with infections of a certain degree of seriousness, for whom a staphylococcal aetiology is demonstrated or suspected (suppurative infections) and methicillin resistance is demonstrated or strongly suspected.

The Committee issues a favourable opinion for inclusion in both the list of covered drugs for outpatients and the list of covered drugs for inpatients approved for use in the treatment of acute bacterial skin and skin structure infections (ABSSSI), only in adult patients with infections of a certain degree of seriousness, for whom a staphylococcal aetiology is demonstrated or suspected (suppurative infections) and methicillin resistance is demonstrated or strongly suspected, and at the MA dosages.

Clinical Added Value

This medicinal product is a range supplement that does not provide any clinical added value (CAV V) compared to the form already listed.